

FORM PTO-1390  
(REV 10-2000)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371**

4002-2729

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

**09/869755**

INTERNATIONAL APPLICATION NO.  
PCT/US00/00590

INTERNATIONAL FILING DATE  
11 January 2000

PRIORITY DATE CLAIMED  
11 January 1999

TITLE OF INVENTION  
TRUNCATED OPEN INTERVERTEBRAL SPACERS

APPLICANT(S) FOR DO/EO/US

Lawrence M. BOYD; J. Kenneth BURKUS; John D. DORCHAK; Bradley T. ESTES, Eddie F. RAY, III

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to promptly begin national examination procedures (35 U.S.C. 371(f)).
4. ☐ The US has been elected by the expiration of 19 months from the priority date (PCT Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
  - a. ☒ is attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ has been communicated by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(X)).
7. ☒ Amendments to the claims of the International Application under PCT Article 19(35 U.S.C. 371(c)(3))
  - a. ☒ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C.371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). (unsigned)
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 16 below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A FIRST preliminary amendment.
- ☐ A SECOND or SUBSEQUENT preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☒ Other items or information:
  - a. PCT Request
  - b. Notification of Transmittal of the International Search Report
  - c. Response to International Search Report
  - d. FORM PCT/IB/304; 332
  - e. International Publication
  - f. Notification Concerning the Filing of Amendments of the Claims
  - g. Written Opinion
  - h. Response to Written Opinion
  - i. International Preliminary Examination Report
  - j. Addition of Applicants/Inventors
  - k. Return Postcard

Express Mail Label No.: EL414479812US

Date of Deposit: 5 July 2001

I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR \$1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Susan R. Geller  
Signature of person mailing paper or fee

U.S. APPLICATION NO. (if known) <b>097/869735</b>	INTERNATIONAL APPLICATION NO. PCT/US00/00590	ATTORNEY'S DOCKET NUMBER <b>4002-2729</b>
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<p>17. <input checked="" type="checkbox"/> The following fees are submitted:</p> <p><b>BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):</b></p> <p>Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO ..... <b>\$1000.00</b></p> <p>International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO ..... <b>\$860.00</b></p> <p>International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO ..... <b>\$710.00</b></p> <p>International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provisions of PCT Article 33(1)-(4) ..... <b>\$690.00</b></p> <p>International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4) ..... <b>\$100.00</b></p> <p style="text-align: center;"><b>ENTER APPROPRIATE BASIC FEE AMOUNT =</b></p> <p>Surcharge of <b>\$130.00</b> for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input checked="" type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).</p> <table border="1" style="width:100%"> <thead> <tr> <th>CLAIMS</th> <th>NUMBER FILED</th> <th>NUMBER EXTRA</th> <th>RATE</th> </tr> </thead> <tbody> <tr> <td>Total claims</td> <td>38 - 20 =</td> <td>18</td> <td>X \$18.00</td> </tr> <tr> <td>Independent claims</td> <td>5 - 3 =</td> <td>2</td> <td>X \$80.00</td> </tr> <tr> <td colspan="3">MULTIPLE DEPENDENT CLAIM(S) (if applicable)</td> <td>+ \$270.00</td> </tr> <tr> <td colspan="3"><b>TOTAL OF ABOVE CALCULATIONS =</b></td> <td><b>\$ 1,304 --</b></td> </tr> <tr> <td colspan="3"><input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.</td> <td><b>\$ N/A</b></td> </tr> <tr> <td colspan="3"><b>SUBTOTAL =</b></td> <td><b>\$ 1,304 --</b></td> </tr> <tr> <td colspan="3">Processing fee of <b>\$130.00</b> for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).</td> <td><b>\$ N/A</b></td> </tr> <tr> <td colspan="3"><b>TOTAL NATIONAL FEE =</b></td> <td><b>\$ 1,304 --</b></td> </tr> <tr> <td colspan="3">Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). <b>\$40.00</b> per property</td> <td><b>\$ N/A</b></td> </tr> <tr> <td colspan="3"><b>TOTAL FEES ENCLOSED =</b></td> <td><b>\$ 1,304 --</b></td> </tr> <tr> <td colspan="3"></td> <td><b>Amount to be refunded:</b></td> </tr> <tr> <td colspan="3"></td> <td><b>charged:</b></td> </tr> </tbody> </table>				CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	Total claims	38 - 20 =	18	X \$18.00	Independent claims	5 - 3 =	2	X \$80.00	MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$270.00	<b>TOTAL OF ABOVE CALCULATIONS =</b>			<b>\$ 1,304 --</b>	<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.			<b>\$ N/A</b>	<b>SUBTOTAL =</b>			<b>\$ 1,304 --</b>	Processing fee of <b>\$130.00</b> for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).			<b>\$ N/A</b>	<b>TOTAL NATIONAL FEE =</b>			<b>\$ 1,304 --</b>	Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). <b>\$40.00</b> per property			<b>\$ N/A</b>	<b>TOTAL FEES ENCLOSED =</b>			<b>\$ 1,304 --</b>				<b>Amount to be refunded:</b>				<b>charged:</b>	<p><b>CALCULATIONS</b>    PTO USE ONLY</p>	
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			<b>charged:</b>																																																						

- a. ☒ A check in the amount of \$ 1,304.00 to cover the above fees is enclosed.
- b. ☐ Please charge my Deposit Account No. 23-3030 in the amount of \$ \_\_\_\_\_ to cover the above fees. A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 23-3030. A duplicate copy of this sheet is enclosed.

**NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.**

SEND ALL CORRESPONDENCE TO:

Kenneth A. GANDY  
WOODARD, EMHARDT, NAUGHTON, MORIARTY & MCNETT  
Bank One Center/Tower, Suite 3700  
111 Monument Circle  
Indianapolis, Indiana 46204 US

*Kenneth A. Gandy*

SIGNATURE:

Kenneth A. Gandy

NAME

#33,386

REGISTRATION NUMBER

IN THE INTERNATIONAL BUREAU OF WIPO

CONFIRMATION COPY  
OF PRIOR FACSIMILE

In re PCT application of	)
SDGI HOLDINGS, INC., et al	)
	)
International Application	)
Number PCT/US00/00590	) Mailing Date
	) 07 September 2000
International Filing Date	)
11 January 2000	) Agent's File
	) Reference:
Title of Invention	) 9904PC2/2221
TRUNCATED OPEN	)
INTERVERTEBRAL SPACERS	)

**RESPONSE TO THE INTERNATIONAL SEARCH REPORT**


The International Bureau  
WIPO  
34, chemin des Colombettes  
1211 Geneva 20  
Switzerland

Dear Sir/Madam:

In response to the International Search Report mailed July 25, 2000, please replace original page 31 with substitute page 31. Claim 36 has been amended. No new matter is believed to be introduced by the aforementioned amendment.

Entry of substitute page 31 is respectfully requested.

Respectfully submitted

By   
Jason J. Schwartz, #43,910  
Woodard, Emhardt, Naughton,  
Moriarty & McNett  
Bank One Center/Tower, Suite 3700  
111 Monument Circle  
Indianapolis, Indiana 46204 US  
(317) 634-3456

DNK-1999-004-PA-PCT2:97426  
Enclosure (Substitute Page 31)

with an interior and exterior surface, at least one of said surfaces of said plate being curved, said occlusion member configured to span to a distal end of the spacer.

5           37.    The tool of claim 36, further comprising a fastener  
attached to said shaft and wherein said plate defines a groove, said  
groove disposed around said fastener so that said plate is slidable  
relative to said housing.

10           38.    The tool of claim 37, wherein said plate has a curved  
superior surface which approximates the outer surface of the  
spacer when said spacer engaging means is engaged to the spacer  
and said occlusion member is blocking the opening of the spacer.

09/869755

JC18 Rec'd PCT/PTO 05 JUL 2001

IN THE INTERNATIONAL BUREAU OF WIPO

In re PCT application of	)
SDGI HOLDINGS, INC., et al	)
	)
International Application	)
Number PCT/US00/00590	) Mailing Date
	) 13 March 2001
International Filing Date	)
11 January 2000	) Agent's File
	) Reference:
Title of Invention	) 9904PC2/2221
TRUNCATED OPEN	)
INTERVERTEBRAL SPACERS	)

**ADDITION OF APPLICANTS/INVENTORS**

The International Bureau  
WIPO  
34, chemin des Colombettes  
1211 Geneva 20  
Switzerland

Dear Sir/Madam:

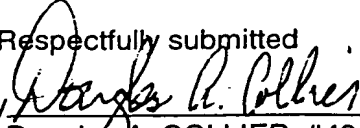
Enclosed please find a substitute page two of the Request, reflecting two additional applicant/inventors as follows:

ESTES, Bradley T.	RAY, III, Eddie F.
5169 Tarrytown Drive	1781 Fernhall Cove
Memphis, Tennessee 38117 US	Collierville, Tennessee 38017 US

We are also enclosing an Appointment of Agent for each applicant/inventor. Please make this change on all appropriate documents and notify all of the necessary offices. We are forwarding a copy of this letter, page two of the Request and the Appointments of Agent to the Receiving Office.

Respectfully submitted

By

  
Douglas A. COLLIER, #43,556  
Woodard, Emhardt, Naughton,  
Moriarty & McNett  
Bank One Center/Tower, Suite 3700  
111 Monument Circle  
Indianapolis, Indiana 46204 US  
(317) 634-3456

120929

cc: RO/US

Enclosures: Page Two of Request, Two Appointments of Agent

Continuation of Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)	
<i>If none of the following sub-boxes is used, this sheet should not be included in the request.</i>	
<p><small>Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)</small></p> <p>BURKUS, J. Kenneth 7162 Williams Hill Road Columbus, Georgia 31904 US</p>	<p>This person is:</p> <p><input type="checkbox"/> applicant only</p> <p><input checked="" type="checkbox"/> applicant and inventor</p> <p><input type="checkbox"/> inventor only (If this check-box is marked, do not fill in below.)</p>
State (that is, country) of nationality: US	State (that is, country) of residence: US
This person is applicant for the purposes of: <input type="checkbox"/> all designated States <input type="checkbox"/> all designated States except the United States of America <input checked="" type="checkbox"/> the United States of America only <input type="checkbox"/> the States indicated in the Supplemental Box	
<p><small>Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)</small></p> <p>DORCHAK, John D. P.O. Box 400 Midland, Georgia 31820 US</p>	<p>This person is:</p> <p><input type="checkbox"/> applicant only</p> <p><input checked="" type="checkbox"/> applicant and inventor</p> <p><input type="checkbox"/> inventor only (If this check-box is marked, do not fill in below.)</p>
State (that is, country) of nationality: US	State (that is, country) of residence: US
This person is applicant for the purposes of: <input type="checkbox"/> all designated States <input type="checkbox"/> all designated States except the United States of America <input checked="" type="checkbox"/> the United States of America only <input type="checkbox"/> the States indicated in the Supplemental Box	
<p><small>Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)</small></p> <p>ESTES, Bradley T. 5169 Tarrytown Drive Memphis, Tennessee 38117 US</p>	<p>This person is:</p> <p><input type="checkbox"/> applicant only</p> <p><input checked="" type="checkbox"/> applicant and inventor</p> <p><input type="checkbox"/> inventor only (If this check-box is marked, do not fill in below.)</p>
State (that is, country) of nationality: US	State (that is, country) of residence: US
This person is applicant for the purposes of: <input type="checkbox"/> all designated States <input type="checkbox"/> all designated States except the United States of America <input checked="" type="checkbox"/> the United States of America only <input type="checkbox"/> the States indicated in the Supplemental Box	
<p><small>Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)</small></p> <p>RAY, III, Eddie F. 1781 Fernhall Cove Collierville, Tennessee 38017 US</p>	<p>This person is:</p> <p><input type="checkbox"/> applicant only</p> <p><input checked="" type="checkbox"/> applicant and inventor</p> <p><input type="checkbox"/> inventor only (If this check-box is marked, do not fill in below.)</p>
State (that is, country) of nationality: US	State (that is, country) of residence: US
This person is applicant for the purposes of: <input type="checkbox"/> all designated States <input type="checkbox"/> all designated States except the United States of America <input checked="" type="checkbox"/> the United States of America only <input type="checkbox"/> the States indicated in the Supplemental Box	
<input type="checkbox"/> Further applicants and/or (further) inventors are indicated on another continuation sheet.	

PCT  
GENERAL POWER OF ATTORNEY

(PCT Rule 90.5)

The undersigned person(s):

Bradley T. Estes  
5169 Tarrytown Drive  
Memphis, Tennessee 38117 US

Hereby appoints the following person as:

X agent                      \_\_\_\_\_ common representative

Name and Address:

Gandy, Kenneth A.  
Woodard, Emhardt, Naughton, Moriarty & McNett  
Bank One Center/Tower, Suite 3700  
111 Monument Circle  
Indianapolis, Indiana 46204  
United States of America

(continued on supplemental page 2)

to represent the undersigned before

X all the competent International Authorities  
\_\_\_\_\_ the International Searching Authority only  
\_\_\_\_\_ the International Preliminary Examining Authority only

in connection with any and all international applications filed by the  
undersigned with the following Office

United States Patent and Trademark Office as Receiving Office  
and to make or receive payments on behalf of the undersigned.

Signature(s):

Bradley T. Estes  
Bradley T. ESTES

Date: 27 July 1998

Supplemental Page 2 to Power of Attorney

WOODARD, Harold R.; EMHARDT, C. David; NAUGHTON, Joseph A., Jr.; MORIARTY, John V.; McNETT, John C.; HENRY, Thomas Q.; DURLACHER, James M.; REEVES, Charles R.; WAGNER, Vincent O.; ZLATOS, Steve; BEREVESKOS, Spiro; BAHRET, William F.; BROWNING, Clifford W.; FRISK, R. Randall; LUEDERS, Daniel J.; GANDY, Kenneth A.; THOMAS, Timothy N.; SISSELMAN, Kerry P.; JONES, Kurt N.; ALLIE, John H.; BANTA, Holiday W.; COLE, Troy J.; PAYNTER, L. Scott; LOWES, J. Andrew; MEYER, Charles J.; SCHANTZ, Matthew R.; COY, Gregory B.; HIDAY, Lisa A.; DANILUCK, John V.; BROWN, Christopher A.; BRANNON, C. John; SCHWARTZ, Jason J.; USHER, Arthur J., IV; COLLIER, Douglas A.; SCHEPERS, Brad A.; MYERS, James B. Jr.; STEVENS, Scott J.; BRADSHAW, John M.; SMITH, C. Amy Ng; SCHMAL, Charles P.; SOWERS, Edward E., and ROWE, James L.



PCT  
GENERAL POWER OF ATTORNEY

(PCT Rule 90.5)

The undersigned person(s):

RAY, III, Eddie F.  
1781 Fernhall Cove  
Collierville, Tennessee 38017 US

Hereby appoints the following person as:

X agent                      \_\_\_\_\_ common representative

Name and Address:

LOWES, J. Andrew  
Woodard, Emhardt, Naughton, Moriarty & McNett  
Bank One Center/Tower, Suite 3700  
111 Monument Circle  
Indianapolis, Indiana 46204  
United States of America

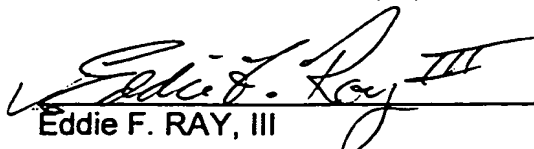
(continued on supplemental page 2)

to represent the undersigned before

X all the competent International Authorities  
\_\_\_\_\_ the International Searching Authority only  
\_\_\_\_\_ the International Preliminary Examining Authority only

in connection with any and all international applications filed by the  
undersigned with the following Office

United States Patent and Trademark Office as Receiving Office  
and to make or receive payments on behalf of the undersigned.

  
\_\_\_\_\_  
Eddie F. RAY, III

Date: 6/9/99

Supplemental Page 2 to Power of Attorney

WOODARD, Harold R.; EMHARDT, C. David; NAUGHTON, Joseph A., Jr.; MORIARTY, John V.; McNETT, John C.; HENRY, Thomas Q.; DURLACHER, James M.; REEVES, Charles R.; WAGNER, Vincent O.; ZLATOS, Steve; BEREVESKOS, Spiro; BAHRET, William F.; BROWNING, Clifford W.; FRISK, R. Randall; LUEDERS, Daniel J.; GANDY, Kenneth A.; THOMAS, Timothy N.; SISSELMAN, Kerry P.; JONES, Kurt N.; ALLIE, John H.; BANTA, Holiday W.; COLE, Troy J.; PAYNTER, L. Scott; LOWES, J. Andrew; MEYER, Charles J.; SCHANTZ, Matthew R.; COY, Gregory B.; HIDAY, Lisa A.; DANILUCK, John V.; BROWN, Christopher A.; BRANNON, C. John; SCHWARTZ, Jason J.; USHER, Arthur J., IV; COLLIER, Douglas A.; SCHEPERS, Brad A.; MYERS, James B. Jr.; STEVENS, Scott J.; BRADSHAW, John M; SMITH, C. Amy Ng; SCHMAL, Charles P.; SOWERS, Edward E., and ROWE, James L.

IN THE EUROPEAN PATENT OFFICE

In re PCT application of	) Authorized Officer:
SDGI HOLDINGS, INC., et al	) Lega D'Incecco
	)
International Application	)
Number PCT/US00/00590	) Mailing Date
	) 28 February 2001
International Filing Date	)
11 January 2000	) Agent's File
	) Reference:
Title of Invention	) 9904PC2/2221
TRUNCATED OPEN	)
INTERVERTEBRAL SPACERS	)

RESPONSE TO WRITTEN OPINION OF THE INTERNATIONAL  
PRELIMINARY EXAMINING AUTHORITY

The International Preliminary Examination Authority  
European Patent Office  
Erhardstrasse 27  
D-80331 Munich  
Germany

Dear Sir/Madam:

In response to the Written Opinion dated 19 January 2001, applicant submits herewith substitute pages 13 and 14 together with the following remarks in support of the above-referenced application. Pages 13 and 14 have been amended to correct certain typographical errors. For example, page 13 has been amended to refer to handle portion "840", in line 19, as handle portion "340", as recited in line 22 of the same page and as seen in FIG. 13.

Moreover, in reference to page 14, the reference numbers in lines 5-9, such as "820", "821", "822", "830", "809", and "805", have been amended to read "320", "321", "322", "330", "309" and "305" as referred to in the specification and as seen in FIG. 14.

**REMARKS**

Claims 1-37 are pending in the application. A negative indication has been given with respect to the novelty of claims 1-5, 7-27 and 35-37. It is asserted in the Opinion that claims 28-34 describe a method of treatment of the human or animal body by surgery and that these claims have not been searched

or further examined. Various other objections have been raised which applicant chooses not to comment on at this time as the requirements of the various countries that the application will be nationalized in may vary.

Turning now to the negative indication with respect to claims 1-5 and 7-27, it is asserted that these claims are not novel over reference D1 (WO -A 98/55052). However, reference D1 does not teach spacers that include all of the features of the spacers as recited in the objected to claims, nor are such spacers even suggested in reference D1, as more fully discussed below.

It is noted that independent claims 1 and 23 recite an interbody fusion spacer or implant system, respectively, wherein each of the arms of the spacer have an end configured to form a region within which an adjacent spacer can nest. Moreover, claim 21 recites an interbody fusion spacer wherein each of the arms of the spacer have an end with a concave surface that forms a region within which an adjacent spacer can nest. In one form of the invention as seen in FIG. 1 of the present application, arms 120 and 121 of spacer 100 each have ends 150 and 151, respectively, that are configured to form a region 170 and 171, respectively, within which an adjacent spacer can nest. At least one border of the nesting region is seen in FIG. 1 as broken lines. In another form of the invention as recited in claim 15, the ends of each of the arms has a surface configured to receive a convex surface of an adjacent spacer.

Conversely, the spacers of reference D1, including the spacers in FIGS. 4, 5 and 11, do not have ends wherein each of the ends are configured to form a region within which an adjacent spacer can nest as required, for example, by claim 1. For example, referring to FIG. 11 of D1, the external profile of the end of arm 581 is circular, thus it is not configured to form a region within which an adjacent spacer can nest. Thus, end of arm 581 of spacer 550 can not and does not form a region within which an adjacent spacer can nest. Moreover, with specific reference to claim 21 of the pending application, reference D1 does not teach or suggest a spacer having arms that each have an end with a concave surface that forms a region within which an adjacent spacer can nest. Additionally, with reference to claim 15, it can be seen in reference D1 that the ends of each of the arms in the spacer of FIG. 11 of D1 do not each have a surface configured to receive a convex surface of an adjacent spacer.

Therefore, spacers recited by the pending claims are nowhere taught or suggested in reference D1.

Turning now to the negative indication with respect to claim 35, it is asserted in the Opinion that claim 35 is not novel over reference D1. However, reference D1 does not teach or suggest a spacer insertion tool that includes all of the features of the spacer insertion tool as recited in claim 35, as more fully discussed below.

Claim 35 recites, and FIG. 15 depicts, a spacer insertion tool that include an occlusion member that is configured to span to a distal end of a spacer. Conversely, as seen in FIG. 28 of reference D1, member 820 is not configured to span to a distal end of the spacer, nor is there any teaching or suggestion elsewhere in the application of such spacer insertion tools.

In view of the foregoing, applicant respectfully requests reconsideration of and withdrawal of the objections in the Written Opinion. Establishment of an International Preliminary Examination Report which is positive in all respects as to claims 1-27 and 35-37 is respectfully requested.

Respectfully submitted

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The spacer engager 319 has any configuration which will engage a spacer. In some embodiments the spacer engager 319 includes a post for engaging a hole in the spacer. The post may have any configuration which will provide for mating engagement with a hole in a spacer. For example, the post may include an engager  
5 319 which is threaded to matingly engage a threaded tool hole. Other embodiments and features may include a sharply pointed tip 319 as shown, or a hexagonal shaped tip. In each case, the engager is shaped and sized to mate engagingly with the tool hole of the spacer. In other embodiments, the spacer engaging means is a pair of prongs having opposite facing spacer engaging members for grasping an  
10 outer surface of the spacer.

The spacer insertion tool 300 also includes an occlusion member 320 for blocking an opening defined in the spacer when the spacer engager 319 is engaged to the spacer. In a preferred embodiment, the occlusion member 320 is slideably engaged to the housing 305, and is extendible from the distal end 307 of the  
15 housing 305 for blocking an opening in the spacer. The occlusion member 320 closes the mouth and channel defined in the spacer 100.

The tool 300 depicted also includes a handle portion 340. The handle portion includes means for slidingly moving the shaft 315 within the housing 305 and for rotating the shaft 315. In the embodiment shown, the means includes a  
20 thumbwheel 341. In some embodiments, the handle portion 340 has a Hudson end attachment 342.

Referring now to Figures 14 and 15, shown are expanded views illustrating an inventive spacer 100 associated with the insertion tool 300 to form an assembly of the invention. As illustrated, insertion tool 300 has an occlusion member 320 having an  
25 interior surface 324 which is convexly curved to complement the concave surfaces of ends 150 and 151 of arms 120 and 121, respectively, of spacer 100. Correspondingly, recess 308 of insertion tool 300 has a concave surface complementary to convexly curved surface 324 of occlusion member 320. Further, occlusion member 320 is of a

length and design sufficient to span to the distal end of the engaged spacer 100, as depicted in Figure 15. Occlusion member 320 can also have a beveled outer end, or an otherwise smoothed outer end, to facilitate rotary insertion.

Referring now to Figure 14, in one embodiment, the occlusion member 320  
5 includes a plate 321 which defines a groove 322. A fastener 330 is engaged to a fastener bore 309 in the housing 305 and the groove 322 is disposed around the fastener 330. In this way, the plate 321 is slideable relative to the housing 305.

As shown, the housing 305 is preferably provided with a recess 308 which  
10 is defined to accept the occlusion member 320 without increasing the effective diameter of the device 300. The occlusion member is also adapted for the best fit with the spacer. For example, the interior surface 324 of the occlusion member would be curved to complement the concave end faces 150 and 151 for engagement. The plate 321 of the occlusion member 320 preferably includes a  
15 curved superior surface 325 which approximates and completes the minor diameter of the dowel 100 when the spacer engager 319 is engaged to the tool engaging hole and the occlusion member 320 is blocking the channel of the spacer 100. Preferably, the plate 321 and the arms 120 and 121 of the spacer 100 will be configured such that when the tool 300 is engaged to the spacer 100, the curved  
20 superior surface 325 will not increase the effective root diameter RD of the threaded outer surface of the spacer 100. This facilitates rotation and screw insertion of the spacer and occlusion member combination into an intervertebral space.

In preferred embodiments, as shown in Figures 14 and 15, the plate  
321 defines a recess 326 surrounding a groove 322. A fastener 330 is  
25 engaged to a fastener bore 309 in the housing 305 and the groove 322 is disposed around the fastener 330. In this way, the plate 321 is slideable relative to the housing 305. The fastener 330 is preferably provided with a post 334, and a plate engaging means or head portion 335. The fastener 330 preferably includes an internal hex as shown for receiving a fastener driving